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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,383	07/16/2003	Alison M. Bendele	A-430H	8520

7590 11/29/2005

U.S. Patent Operations/ DKS (WA)
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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,383	BENDELE ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 27-44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 27-44 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 27-44 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 27-30, 33-37, 41 and 42, in so far as they are drawn to method of treatment of neurological conditions with a TNF antagonist that is sTNFR II Fc, classified in class 514, subclass 12.

II. Claims 27-30, 33, 37, 38, 41 and 42, in so far as they are drawn to method of treatment of neurological conditions with a TNF antagonist that is cA2 anti-TNF antibody, classified in class 514, subclass 12.

III. Claims 27-30, 33, 41 and 42, in so far as they are drawn to method of treatment of neurological conditions with a TNF antagonist that is CDP 571 anti-TNF antibody, classified in class 514, subclass 12.

IV. Claim 31, in so far as it is drawn to method of treatment of muscle disorder with a TNF antagonist that is sTNFR II Fc, classified in class 514, subclass 12.

V. Claim 31, in so far as it is drawn to method of treatment of muscle disorder with a TNF antagonist that is cA2 anti-TNF antibody, classified in class 514, subclass 12.

VI. Claim 31, in so far as it is drawn to method of treatment of muscle disorder with a TNF antagonist that is CDP 571 anti-TNF antibody, classified in class 514, subclass 12.

VII. Claims 32, 39, 40 and 43, in so far as they are drawn to method of treatment of ocular disease with a TNF antagonist that is sTNFR II Fc, classified in class 514, subclass 12.

VIII. Claims 32, 39, 40 and 43, in so far as they are drawn to method of treatment of ocular disease with a TNF antagonist that is cA2 anti-TNF antibody, classified in class 514, subclass 12.

IX. Claims 32, 39, 40 and 43, in so far as they are drawn to method of treatment of ocular disease with a TNF antagonist that is CDP 571 anti-TNF antibody, classified in class 514, subclass 12.

X. Claim 44, in so far as it is drawn to method of treatment of hyperalgesia with a TNF antagonist that is sTNFR II Fc, classified in class 514, subclass 12.

XI. Claim 44, in so far as it is drawn to method of treatment of hyperalgesia with a TNF antagonist that is cA2 anti-TNF antibody, classified in class 514, subclass 12.

XII. Claim 44, in so far as it is drawn to method of treatment of hyperalgesia with a TNF antagonist that is CDP 571 anti-TNF antibody, classified in class 514, subclass 12.

The inventions are distinct, each from the other because of the following reasons:

The methods of treatment of the Inventions of Groups I-III, IV-VI, VII-IX and X-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects

(MPEP § 806.04, MPEP § 808.01). In the instant case, the diseases or disorders to be treated, neurological, muscle, ocular and hyperalgesia, respectively, are diseases or disorders of different cells or tissues and have different symptoms and etiologies, and are therefore patently distinct, and each would require a separate search.

The inventions of Group A (I, IV, VII and X), Group B (II, V, VIII and XI) and Group C (III, VI, IX and XII) are related in that the compounds used in the methods of treatment (sTNFR II Fc, cA2 anti-TNF antibody and CDP 571 anti-TNF antibody, respectively), are all TNF antagonists. However, they are patentably distinct because they have different amino acid sequences, and would require separate searches.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Species Elections

If any of Group I-III is elected, a species election is required.

This application contains claims directed to the following patentably distinct species of the claimed invention: neurological condition selected from epileptic disorders, brain injury from trauma, hemorrhage or stroke, neuroinflammatory disease, and infection.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 27, 29, 33-38 and 41 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected from both groups consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

EILEEN B. O'HARA
PATENT EXAMINER